

2/10/21
AS

(b) evaporating [bulk] a proportion of the solvent from the mixture to obtain a syrup;
and
(c) exposing the syrup to [a pressure and temperature sufficient to cause] reduced pressure at a temperature that causes boiling of the syrup at said pressure, resulting in formation of an FGM[; and
(d) optionally removing the residual moisture].

A 6

6. (Amended) The method according to claim 3, wherein the carbohydrate is selected from the group consisting of glucose, maltulose, iso-maltulose, lactulose, [and] sucrose, maltose, lactose, isomaltose [and sugar alcohols thereof, maltitol, lactitol, palatin], a mixture of α -D-glucopyranosyl-mannitol, and α -D-glucopyranosyl-sorbitol, and its individual sugar alcohols, non-reducing glycosides of polyhydroxy compounds selected from sugar alcohols, other straight chain polyalcohols], raffinose, stachyose, melezitose, [and] dextran, fructose, galactose, mannose, cellobiose, mannobiase, and sugar alcohols obtained by reduction of disaccharides.

A

8. (Amended) The method according to claim 1, wherein the solvent comprised in the initial mixture is aqueous.

Sub F1

9. (Amended) The method according to claim 8, wherein the solvent comprised in the initial mixture is [selected from the group consisting of biologically acceptable buffers] an aqueous buffer.

AS

10. (Amended) The method according to claim 1, wherein the solvent comprised in the initial mixture is organic.

AS

12. The method according to claim 1, wherein the solvent comprised in the initial mixture is a combination of aqueous and organic [solvents] liquids.

13. (Amended) The method according to claim 8, wherein the solvent is present in the initial mixture in an amount of about 5% to 95% by volume.

~~Sub. E2~~ 14. (Amended) The method according to claim 1, wherein the evaporation in step (b) occurs at [a] an external temperature higher than [ambient temperature] 25°C.

~~A8~~ 15. (Amended) The method according to claim [14] 1, wherein the evaporation in step (b) occurs at an external temperature [is] of about 0°C to 90°C.

16. (Amended) The method according to claim [14] 1, wherein the evaporation in step (b) occurs at an external temperature [is] of about 15°C to 60°C.

~~Sub. E2~~ 17. (Amended) The method according to claim 14, wherein the evaporation in step (b) occurs at an external temperature [is] of about 25°C to 45°C.

~~A8~~ 18. (Amended) The method according to claim 1, wherein the evaporation in step (b) [is under conditions sufficient to remove] results in removal of 5-95% of the solvent.

~~Sub. D2~~ 19. (Amended) The method according to claim 1, wherein the evaporation during step (b) occurs at [a pressure that is less than ambient] reduced external pressure.

20. (Amended) The method according to claim 19, wherein the external pressure during step (b) is about 0.1 to 30 [Torr/]mm Hg.

21. (Amended) The method according to claim 19, wherein the external pressure during step (b) is about 1 to 20 [Torr/]mm Hg.

A 8
~~22. (Amended) The method according to claim 19, wherein the external pressure during step (b) is about 7.5 to 12.5 [Torr/]mm Hg.~~

~~23. (Amended) The method according to claim 19, wherein the external pressure during step (b) is about 10 [Torr/]mm Hg.~~

Sub D3
J. W. C. 3
~~26. (Amended) The method according to claim 1, wherein the pressure during step (c) is [about 0.01 to] below 30 [Torr/]mm Hg.~~

A 9
~~27. (Amended) The method according to claim 1, wherein the pressure during step (c) is about 0.01 to 10 [Torr/]mm Hg.~~

A 9
~~28. (Amended) The method according to claim 1, wherein the pressure during step (c) is about 0.01 to 0.5 [Torr/]mm Hg.~~

Sub D4
J. W. C. 4
~~29. (Amended) The method according to claim 1, wherein the pressure during step (c) is about 0.05 [Torr/]mm Hg.~~

Sub D4
J. W. C. 4
~~30. (Amended) The method according to claim 1, wherein the boiling during step (c) occurs at an external temperature above [ambient temperature] 25°C.~~

A 10
~~36. (Amended) The method according to claim 1, further comprising the step of adding at least one additive [during step (a)] to the mixture before step (c).~~

A 11
~~40. (Amended) The method according to claim 36, wherein the additive is at least one [decomposing] salt that decomposes under reduced pressure to give a gaseous product.~~

A12
~~Asub~~
42. The method according to claim 36, wherein the additive is at least one volatile organic [solvent] liquid.

A13
~~Asub~~
47. (Amended) The method according to claim 44, wherein the foam stabilizing agent is a surface-active [an] amphipathic molecule.

~~Asub~~
49. (Amended) The method according to claim 1, further comprising adding a substance [during step (a) or step (b)] ~~to be preserved to the mixture before formation of the FGM.~~

54. (Amended) The method according to [claim 53, wherein the biological modifier is selected from the group consisting of subcellular compositions, cells, bacteria, viruses and molecules] ~~claim 49, wherein the substance to be preserved is selected from the group consisting of cells, subcellular components, bacteria, and viruses.~~

A15
C6
55. (Amended) The method according to [claim 54, wherein the molecules are] ~~claim 49, wherein the substance to be preserved is selected from the group consisting of lipids, [organics,] proteins, [and] peptides [(synthetic and natural)], peptide mimetics, [hormones, D and L amino acid polymers], oligosaccharides, [polysaccharides, nucleotides,] oligonucleotides [and nucleic acids, including DNA and RNA], and protein nucleic acid hybrids[, and small molecules and physiologically active analogs thereof].~~

56. (Amended) The method according to claim 55, wherein the [proteins are] ~~substance to be preserved is a protein or peptide selected from the group consisting of enzymes, [biopharmaceuticals, growth hormones, growth factors, insulin,] monoclonal antibodies, interferons, interleukins [and] cytokines, hormones, and other growth factors.~~

Sub. 6
1/10/04
A15
AC1
Sub. 3
Sub. 16
A16

57. (Amended) The method according to claim 50, wherein the substance to be preserved is a vaccine.

58. (Amended) The method according to claim 57, wherein the vaccine comprises a component selected from the group consisting of live and attenuated viruses, nucleotide vectors encoding antigens, live and attenuated bacteria, antigens, antigens [plus] mixed with adjuvants, and haptens coupled to carriers.

59. (Amended) [The method according to claim 50, further comprising the step of reconstituting the] A method for providing a reconstituted [bioactive] substance [in a solvent], comprising producing an FGM according to the method of claim 1 into which the substance is incorporated, and then contacting the FGM with sufficient solvent for the glass matrix forming material to dissolve the material.

61. (Amended) The method according to claim 59, wherein the solvent is [a biologically acceptable] an aqueous buffer.

62. (Amended) A method for [stably incorporating at least one substance within thin, foamed glass matrices (FGMs)] preserving a substance within a thin, foamed glass matrix (FGM) comprising the steps of:

- (a) preparing an initial mixture comprising at least one glass matrix-forming material, [at least one substance to be incorporated and at least one solvent including at least one solvent for the glass matrix-forming material and at least one solvent for the substance], a solvent therefor, and the substance to be preserved;
- (b) evaporating [bulk] a proportion of the solvent from the mixture to obtain a syrup; and
- (c) exposing the syrup to a pressure and temperature [sufficient to cause] that causes boiling of the syrup, resulting in formation of an FGM[; and

(d) optionally removing residual moisture].

63. (Amended) The method according to claim 62, wherein the solvent is a solvent for both the glass matrix-forming material and [the solvent for] the substance [are the same solvent].

64. (Amended) The method according to claim 62, wherein the [solvent] mixture prepared in step a) comprises different solvents for the glass matrix-forming material and [the solvent for] the substance [are different solvents].

65. (Amended) A method for producing [stable, dried, readily soluble single dosage] a single dose of a [bioactive] substance, comprising the steps of:

(a) preparing an initial mixture comprising at least one glass matrix-forming material, [at least one substance to be incorporated and at least one solvent including at least one solvent for the glass matrix-forming material and at least one solvent for the substance], a solvent therefor, and the substance;

- (b) evaporating [bulk] a proportion of the solvent from the mixture to obtain a syrup;
- (c) exposing the syrup to a pressure and temperature [sufficient to cause] that causes

66. (Amended) The method according to claim 65, wherein the solvent is a solvent for both the glass matrix-forming material and [the solvent for] the substance [are the same solvent].

67. (Amended) The method according to claim 65, wherein the [solvent] mixture prepared in step a) comprises different solvents for the glass matrix-forming material and [the solvent for] the substance [are different solvents].

Sub. D10
Sub. C9

69. (Amended) The method according to claim 65, further comprising [reconstituting the FRG in a suitable solvent] contacting the FGM with sufficient solvent for the glass matrix forming material to dissolve the material.

Sub. C9

70. (Amended) A method for reconstituting a substance that is incorporated into thin, foam glass matrices (FGMs), comprising [adding a suitable solvent to the FGMs in an amount sufficient to attain a desired concentration of the substance] contacting the FGMs with sufficient solvent for glass matrix forming material in the FGMs to dissolve the material.

Sub. C9
Sub. A7

71. (Amended) A [composition comprising a] thin, foamed glass matrix (FGM) obtainable by the method of claim 1.

A7

72. (Amended) A composition comprising at least one substance [incorporated into thin, foamed glass matrices (FGMs)] preserved in an FGM, obtainable by the method of claim 62, wherein step (c) is conducted at reduced pressure.

73. (Amended) A [composition obtainable by reconstituting the thin foamed glass matrices (FGMs) of] reconstituted substance obtainable by preserving the substance within an FGM according to claim 62 wherein step (c) is conducted at reduced pressure, and then contacting the FGM with sufficient solvent for the glass matrix forming material to dissolve the material.

Sub. B7
A8

75. (Amended) A [composition obtainable by reconstituting the thin, foamed glass matrices (FGMs) of] reconstituted single dose of a biological substance obtainable by producing a single dose of a substance preserved within an FGM according to claim 65 wherein step (c) is conducted at reduced pressure, and then contacting the FGM with sufficient solvent for the glass matrix forming material to dissolve the material.

Please cancel the following claims without prejudice: Nos. 11, 24, 25, 43, 50, 51, 52, 53, 60, 68, 74, 76, and 77.

Please add the following new claims:

Sub. D12
--78. (New) The method according to claim 1, further comprising reducing residual moisture from the FGM formed in step c).

Sub. D12
79. (New) The method according to claim 1, wherein the syrup has a viscosity of at least 10^6 Pascal seconds.

Sub. D9
80. (New) The method according to claim 3, wherein the carbohydrate is selected from the group consisting of trehalose, maltitol, lactitol, palatinit, GPS, and GPM.

Sub. C12
A19
81. (New) The method according to claim 49, wherein the substance to be preserved is a physiologically active small molecule selected from the group consisting of Cyclosporin A and other immunosuppressive agents, beta blockers, H2 agonists, H2 antagonists, steroids, sex hormones, Phenobarbitals, analgesics, antimicrobials, antivirals, antiinflammatories, antiarthritics, antispasmodics, antidepressants, antipsychotics, tranquilizers, antianxiety drugs, narcotics, antiparkinsonism agents, cholinergic agonists, chemotherapeutics, appetite suppressants, anticholinergics, antiemetics, antihistaminics, antimigraine agents, vasodilators, contraceptives, antithrombotic agents, diuretics, antihypertensives, cardiovascular drugs, and opioids.

Sub. F9
82. (new) The method according to claim 58, wherein the component is Hepatitis B Surface Antigen, measles virus, or oral polio virus.

83. (New) The method according to claim 62, further comprising reducing residual moisture from the FGM formed in step c).

84. (New) The method according to claim 62, wherein the substance to be preserved is in suspension in the mixture.

85. (New) The method according to claim 62, wherein the substance to be preserved is dissolved in the mixture.

86. (New) The composition of claim 72, wherein the substance is selected from the group consisting of cells, subcellular components, bacteria, and viruses.

87 (New) The composition of claim 72, wherein the substance is selected from the group consisting of lipids, proteins, peptides, peptide mimetics, oligosaccharides, oligonucleotides, protein nucleic acid hybrids, and physiologically active small molecules.

88. (New) The composition of claim 72, wherein the substance is a protein or peptide selected from the group consisting of enzymes, monoclonal antibodies, interferons, interleukins, cytokines, hormones, and other growth factors.

89. (New) The composition of claim 72, wherein the substance is a vaccine comprising a component selected from the group consisting of live and attenuated viruses, nucleotide vectors encoding antigens, live and attenuated bacteria, antigens, antigens mixed with adjuvants, and haptens coupled to carriers.

90. (New) The composition of claim 72, having a residual moisture content of about 0.1 to 5% (w/w).

91. (New) A method for producing thin, foamed glass matrices (FGMs), comprising the steps of:

- (a) preparing an initial mixture comprising at least one glass matrix-forming carbohydrate, a solvent therefor, and at least one foam-promoting additive which is a volatile salt or a salt that decomposes at reduced pressure to give a gaseous product;
- (b) evaporating a proportion of the solvent from the mixture to obtain a syrup;
- (c) exposing the syrup to a pressure and temperature that causes boiling of the syrup, thereby forming an FGM.

92. (New) The method of claim 91, wherein the carbohydrate is trehalose, lactitol or palatinit.

93. (New) An FGM incorporating a substance to be preserved, formed according to the method of claim 91.

94. (New) A method for producing thin, foamed glass matrices (FGMs), comprising the steps of:

- (a) preparing an initial mixture comprising at least one glass matrix-forming carbohydrate, carbohydrate alcohol or carbohydrate derivative, an aqueous solvent therefor, and a foam-promoting additive which is a volatile organic solvent;
- (b) evaporating a proportion of the aqueous and organic solvents from the mixture to obtain a syrup;
- (c) exposing the syrup to a pressure and temperature that causes boiling of the syrup, thereby forming an FGM.

95. (New) The method of claim 94, wherein the carbohydrate is trehalose, lactitol or palatinit.